

APPENDIX B – CLEAN SET OF ALL PENDING CLAIMS

1. A composition for treating pain comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof; and one or more Drug Useful in the Treatment of Pain in a weight ratio of from about one part olanzapine to from about one (1) part to about one thousand (1000) parts Drug Useful in the Treatment of Pain.
2. A composition of claim 1 wherein the Drug Useful in the Treatment of Pain is an NSAIDS.
3. A composition of claim 2 wherein the NSAIDS is selected from the group consisting of aspirin, indomethacin, ibuprofen, naproxen, fenoprofen, tolmetin, sulindac, meclofenamate, keoprofen, piroxicam, flurbiprofen, and diclofenac or a pharmaceutically acceptable salt thereof.
4. A composition of claim 1 wherein olanzapine is Form II olanzapine polymorph having a typical x-ray diffraction pattern as follows, wherein d represents the interplanar spacing:

d
10.2689
8.577
7.4721
7.125
6.1459
6.071
5.4849
5.2181
5.1251
4.9874
4.7665
4.7158
4.4787
4.3307
4.2294
4.141
3.9873
3.7206
3.5645
3.5366
3.3828
3.2516
3.134
3.0848

3.0638

3.0111

2.8739

2.8102

2.7217

2.6432

2.6007.

5. A composition of claim 4 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of aspirin, ibuprofen, and naproxen.

6. A composition of claim 1 wherein the weight ratio of olanzapine to Drug Useful in the Treatment of Pain is from about one part olanzapine to from about one (1) to about one hundred (100) parts Drug Useful in the Treatment of Pain.

7. A composition of claim 6 wherein the weight ratio is from about one part olanzapine to from about one (1) to about thirty (30) parts Drug Useful in the Treatment of Pain.

8. A composition of claim 7 wherein the weight ratio is from about one part olanzapine to from about one (1) to about ten (10) parts Drug Useful in the Treatment of Pain.

9. A composition of claim 8 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of morphine, acetaminophen, ibuprofen, and diclofenac.

10. A composition of claim 1 wherein the Drug Useful in the Treatment of Pain is an opioid compound.

11. A composition of claim 4 wherein the Drug Useful in the Treatment of Pain is an opioid compound.

12. A composition of claim 7 wherein the Drug Useful in the Treatment of Pain is an opioid compound.

13. A composition of claim 10 wherein the opioid compound is selected from the group consisting of morphine, codeine, meperidine, methadone, propoxyphene, levorphanol, hydromorphone, oxymorphone, oxycodone, brompton's cocktail, pentazocine, butorphanol, nabuphine, and buprenorphine.

Serial No. 09/935,513

14. A composition of claim 13 wherein the opioid compound is selected from the group consisting of morphine, oxymorphone, oxycodone, hydromorphone, codeine, and methadone.

15. (once amended) A composition of claim 1 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of Tylenol #3, tricyclic antidepressants, anticonvulsants, serotonin reuptake inhibitors, mixed serotonin-norepinephrine reuptake inhibitors, serotonin receptor agonists and antagonists, cholinergic analgesics, and neurokinin antagonists.

16. A composition of claim 4 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of Tylenol #3, tricyclic antidepressants, anticonvulsants, and serotonin reuptake inhibitors, mixed serotonin-norepinephrine reuptake inhibitors analgesics, and neurokinin antagonists.

17. A composition of claim 16 wherein the Drug Useful in the Treatment of Pain is a tricyclic antidepressant.

18. A composition of claim 1 wherein the Drug Useful in the Treatment of Pain is an alpha adrenergic compound.

19. A composition of claim 18 wherein the central alpha-adrenergic active compound is Clonidine or a pharmaceutically acceptable salt thereof.

20. A composition of claim 4 wherein the Drug Useful in the Treatment of Pain is an alpha adrenergic compound.

21. A composition of claim 7 wherein the Drug Useful in the Treatment of Pain is an alpha adrenergic compound.

22. A composition of claim 1 wherein the composition can provide a synergistic analgesic effect.

23. A composition for treating pain comprising olanzapine, or a pharmaceutically acceptable salt or solvate thereof; and ibuprofen, or a pharmaceutically acceptable salt

Serial No. 09/935,513

thereof, in a weight ratio of about one part olanzapine to from about one (1) to about one thousand (1000) parts ibuprofen.

24. A composition of claim 23 wherein the olanzapine is Form II olanzapine polymorph.

25. A composition of claim 23 wherein the weight ratio is about one part olanzapine to from about one (1) to about one hundred (100) parts ibuprofen.

26. A composition of claim 23 wherein the weight ratio is about one part olanzapine to from about one (1) to about thirty (30) parts ibuprofen.

27. A composition of claim 26 wherein the weight ratio is about one part olanzapine to from about one (1) to about ten (10) parts ibuprofen.

28. A method for treating pain comprising administering an analgesic dose of a composition comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof; and one or more Drug Useful in the Treatment of Pain in a weight ratio of olanzapine to Drug Useful in the Treatment of Pain of from about one part olanzapine to from about one (1) to about one thousand (1000) parts Drug Useful in the Treatment of Pain.

29. A method of claim 28 wherein the Drug Useful in the Treatment of Pain is an NSAIDS.

30. A method of claim 28 wherein the weight ratio of olanzapine to Drug Useful in the Treatment of Pain is from about one (1) part olanzapine to from about one (1) to about one hundred (100) parts Drug Useful in the Treatment of Pain.

31. A method of claim 28 wherein the weight ratio of olanzapine to Drug Useful in the Treatment of Pain is from about one (1) part olanzapine to from about one (1) to about thirty (30) parts Drug Useful in the Treatment of Pain.

Serial No. 09/935,513

32. A method of claim 28 wherein olanzapine is Form II olanzapine polymorph having a typical x-ray diffraction pattern as follows, wherein d represents the interplanar spacing:

d

10.2689

8.577

7.4721

7.125

6.1459

6.071

5.4849

5.2181

5.1251

4.9874

4.7665

4.7158

4.4787

4.3307

4.2294

4.141

3.9873

3.7206

3.5645

3.5366

3.3828

3.2516

3.134

3.0848

3.0638

3.0111

2.8739

2.8102

2.7217

2.6432

2.6007

33. A method of claim 28 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of alpha adrenergic compounds and opioid compounds.

34. A method of claim 28 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of Tylenol #3, tricyclic antidepressants, anticonvulsants, and serotonin reuptake inhibitors, mixed serotonin-norepinephrine reuptake inhibitors, analgesics, and neurokinin antagonists.

35. A method of claim 28 wherein pain is neuropathic pain.

36. A method of claim 28 wherein pain is nociceptive pain.
37. A method of claim 28 wherein the pain is acute pain.
38. A method for treating pain comprising administering an analgesic dose of a composition comprising olanzapine, or a pharmaceutically acceptable salt or solvate thereof, and ibuprofen, or a pharmaceutically acceptable salt thereof, in a weight ratio of about one part olanzapine to from about one (1) to about one thousand (1000) parts ibuprofen.
39. A method of claim 38 wherein the olanzapine is Form II olanzapine polymorph.
40. A method of claim 38 wherein the weight ratio of olanzapine to ibuprofen is about one (1) part olanzapine to from about one (1) to about one hundred (100) parts ibuprofen.
41. A method of claim 40 wherein the weight ratio of olanzapine to ibuprofen is about one (1) part olanzapine to from about one (1) to about thirty (30) parts ibuprofen.
42. A method of claim 38 wherein the pain is neuropathic pain.
43. A method of claim 38 wherein the pain is nociceptive pain.
44. A method of claim 38 wherein the pain is acute pain.
60. (once amended) A pharmaceutical composition comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof; and a serotonin reuptake inhibitor, in a weight ratio of about one (1) part olanzapine to about one (1) to about one hundred (100) parts serotonin reuptake inhibitor.
61. (once amended) A pharmaceutical composition of claim 60 wherein the serotonin reuptake inhibitor is fluoxetine, or a pharmaceutically acceptable salt thereof.
62. A pharmaceutical composition of claim 60 wherein the serotonin reuptake inhibitor is paroxetine.
63. A pharmaceutical composition of claim 60 wherein the serotonin reuptake inhibitor is citalopram.
64. A pharmaceutical composition of claim 60 wherein the serotonin reuptake inhibitor is sertraline.
65. (once amended) A pharmaceutical composition comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof; and a mixed serotonin-norepinephrine

Serial No. 09/935,513

reuptake inhibitor, in a weight ratio of about one (1) part olanzapine to about one (1) to about one hundred (100) parts mixed serotonin-norepinephrine reuptake inhibitor.

66. A pharmaceutical composition of claim 65 wherein the mixed serotonin-norepinephrine reuptake inhibitor is venlafaxine.

67. A pharmaceutical composition of claim 65 wherein the mixed serotonin-norepinephrine reuptake inhibitor is duloxetine.

81. (once amended) A pharmaceutical composition in unit dose form comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof; and a serotonin reuptake inhibitor wherein the weight ratio of olanzapine to serotonin reuptake inhibitor is about one (1) part olanzapine to about one (1) to about ten (10) parts serotonin reuptake inhibitor.

82. (once amended) A pharmaceutical composition in unit dose form of claim 81 wherein the serotonin reuptake inhibitor is fluoxetine, or a pharmaceutically acceptable salt thereof.

83. A pharmaceutical composition in unit dose form of claim 81 wherein the serotonin reuptake inhibitor is paroxetine.

84. A pharmaceutical composition in unit dose form of claim 81 wherein the serotonin reuptake inhibitor is citalopram.

85. A pharmaceutical composition in unit dose form of claim 81 wherein the serotonin reuptake inhibitor is sertraline.

86. (once amended) A pharmaceutical composition in unit dose form comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof; and a mixed serotonin-norepinephrine reuptake inhibitor wherein the weight ratio of olanzapine to mixed serotonin-norepinephrine reuptake inhibitor is about one (1) part olanzapine to about one (1) to about ten (10) parts mixed serotonin-norepinephrine reuptake inhibitor.

87. A pharmaceutical composition in unit dose form of claim 86 wherein the mixed serotonin-norepinephrine reuptake inhibitor is venlafaxine.

88. A pharmaceutical composition in unit dose form of claim 86 wherein the mixed serotonin-norepinephrine reuptake inhibitor is duloxetine.

89. A pharmaceutical composition in unit dose form of claim 82 wherein the composition is associated with a pharmaceutically acceptable excipient.

90. A pharmaceutical composition in unit dose form of claim 89 wherein the unit dose is a tablet.

91. A pharmaceutical composition in unit dose form of claim 89 wherein the unit dose is a capsule.